

REMARKS

Claims 16 and 20 to 29 are now pending. In the current Office Action, the Examiner has rejected the pending claims under 35 U.S.C. §103(a), as obvious over U.S. Patent No. 5,951,599 to McCrory in view of Chuter et al. (*J. Vasc. Surg* 2000., 31:122-133), May et al. (*J. Vasc. Surg* 2000., 32:124-129), and U.S. Patent No. 5,695,480 to Evans.

The rejections are addressed in full by the arguments that follow.

THE REJECTION UNDER 35 U.S.C. §103(A) AS OBVIOUS OVER WO 85/00969:

The Examiner has rejected claims 16 and 20 to 29 as obvious over U.S. Patent No. 5,951,599 to McCrory (hereinafter "McCrory") in view of Chuter et al. (hereinafter "Chuter"), May et al. (hereinafter "May"), and U.S. Patent No. 5,695,480 to Evans (hereinafter "Evans"). The Examiner has cited McCrory as disclosing occlusive systems that include a stent for deployment in the parent vessel and a polymeric embolizing composition. The Examiner acknowledges that McCrory fails to disclose either a stent graft or a kit of parts including such and relies upon the teaching of Chuter, May and Evans to provide the missing teaching. The Examiner asserts that the combined disclosure of these references renders the pending claims obvious. Applicants disagree.

As the Examiner is aware, to establish *prima facie* obviousness, three criteria must be met. First, there must be some suggestion or motivation in the prior art to modify the reference or combine the reference teachings. Secondly, there must be a reasonable expectation of success. And finally, the reference or references must teach or suggest all the claim limitations. See M.P.E.P. § 2143. In the present instance, there is no motivation to combine the teaching of the cited references and, were such a combination to be made, the combined disclosure would clearly fail to teach or suggest every element of the claimed invention.

Independent claim 16 recites a kit comprising a fluid composition that forms a coherent mass in the presence of blood and adheres to the vascular surface and/or the surface of the endovascular prostheses and, serving as the endovascular prosthesis, a stent graft capable of inhibiting blood flow into an abdominal aortic aneurysm. As discussed in the background section of the application, the use of the recited fluid in conjunction with a stent

graft provides a significant improvement over currently used treatments for abdominal aortic aneurysms as the combined fluid and stent graft are capable of sealing the endoleaks that frequently arise in conventional treatment methods.

In contrast to the claimed invention, McCrory teaches a modified stent having a first portion that is permeable to blood flow and a second portion that is not. This is in direct contrast to the stent grafts taught by May and Chutter. The stent grafts disclosed therein and as known in the art are comprised of a single contiguous blood impermeable graft portion that is "capped" at the proximal and distal ends with conventional stents. Such stent grafts are known for their increased ability to prevent endoleakage.

The McCrory device is designed for use in the repair of aneurysms having a discrete "neck." That is to say, the aneurysms for which McCrory is intended are bubble-like sacs and extrude from one specific location in the lumen. This aspect of the McCrory device can be clearly seen in the drawings provided in the reference and in the discussion on column 2, lines 21 to 33. McCrory stresses the advantages of its two portion device by pointing out the ability of the device to allow for blood flow to perforating vessels through the permeable portions of the stent, see column 4, line 66, to column 5, line 10.

While McCrory does acknowledge that the number of perforating vessels is reduced in the abdominal vasculature, this disclosure does not in anyway detract from the references focus. Furthermore, there is no suggestion in McCrory that the device taught therein should be or could be modified for use with aneurysms that encompass significant portions or even the entire radius of the lumen and have no specific "neck" or discrete location as abdominal aortic aneurysms frequently do.

In the Office Action under reply, the Examiner has stated that "it is *prima facie* obvious to combine two composition each of which is taught by the prior art to be useful for the same purpose in order to form a third composition that is to be used for the very same purpose." Applicants submit that the device taught by McCrory and those taught by May and Chutter are not useful for the same purpose, i.e., the treatment of abdominal aortic aneurysms. Modification of the McCrory device to substitute a stent graft for the modified graft taught there in would destroy the McCrory device's ability to allow blood flow into the perforating vessels, a result that directly contradicts one of the specific advantages of the

McCrory device. Thus, McCrory actually teaches away from the combination suggested by the Examiner. Given the differences in the device of McCrory and the May and Chutter graft stents, there would be no motivation to combine the teaching of the references. They are simply not useful for the same purpose.

The proposed combination of references also fails to satisfy the requirement for a reasonable expectation of success. A device produced based on the combined teaching of the references would not be reasonably expected to successfully function as intended by the references. Assuming *arguendo* that the two-portion stent in McCrory was replaced with a graft stent, the resulting occlusive system would not provide for the passage of blood to the peripheral vasculature. This failing of the new "modified" system would render it unsuitable for treatment of intracranial aneurysms, one of the specifically discussed applications of the McCrory device. Similarly, substitution of the McCrory device for the stent grafts used in May and Chutter would similarly be expected to fail, as the McCrory stent does not provide the same ability to protect against endoleakage.

Replacement of the specifically designed McCrory stent with a graft stent would in no way be obvious as such a replacement would destroy the intended functionality of the McCrory device. Consequently, there would be no motivation to make such a substitution and no reasonable expectation of success should such a substitution be made. The McCrory device is structurally different from the stent grafts of May and Chutter, i.e., the two-portion design as opposed to a contiguous blood impermeable stent graft, is intended to for a different purpose, i.e., the treatment of discrete, bubble-like aneurysms having a specific neck, and has different specific advantages, i.e., allowing for passage of blood to the peripheral vasculature. It is only through impermissible hindsight that the Examiner is able to arrive at the claimed invention from the combined teaching of the references.

The Examiner has failed to establish *prima facie* obviousness as there is no motivation to combine the teaching of McCrory with that of May and Chutter. As Evans fails to supply any discussion regarding the stent graft or the fluid, the combination of references does not teach each and every element of independent claim 16 or any claim dependent thereon, i.e., claims 20 to 29. Reconsideration and withdrawal of the rejection is in order and is respectfully requested.

CONCLUSION

Accordingly, for the reasons set forth above, it is submitted that reconsideration of the application in view of the above remarks will place the application in condition for allowance and such reconsideration and allowance are requested. A Notice of Appeal is being submitted herewith to prevent inadvertent abandonment of the application.

If the Examiner has any questions concerning this communication, please contact the undersigned at (650) 622-2300.

Respectfully submitted,

Date:

5/20/03

By:

J. Elin Hartrum
J. Elin Hartrum
Registration No. 43,663

BURNS, DOANE, SWECKER & MATHIS, L.L.P.
P.O. Box 1404
Alexandria, Virginia 22313-1404
(650) 622-2300